

**REMARKS**

**Claims Under Consideration**

Claims 1-8, 10 and 60-72 are pending in the application, of which, according to the Office Action, claims 8, 10, 60, 61, and 72 are currently under examination.

At page 2 of the Office Action, the Examiner states that claims 62-71, added in the June 9, 2004 Amendment, are withdrawn from consideration as being directed to an invention that is independent or distinct from the elected invention.

Specifically, the Examiner contends that claims 62-71 recite processes of making the products of claims 8, 10, 11, 60, 61, and 72. The Examiner also contends that the products of claims 8, 10, 11, 60, 61, and 72 can be made by other materially different processes, such as by transforming a microorganism with nitrilase and nitrile hydratase genes. Thus, the Examiner has withdrawn claims 62-71 as being directed to a non-elected invention.

Applicants request reconsideration as to claims 62 and 64-71. These claims are product-by-process claims and not process claims as the Examiner suggests. Thus, the Examiner's restriction as to these claims is improper. That is, the patentability of a product-by-process claim is based upon the product, and not the process. Thus, these claims are properly presented in this application in which the corresponding product claims were elected. See MPEP § 806.05(f). Accordingly, Applicants request that product-by-process claims 62 and 64-71 be examined in this application.

With regard to claim 63, directed to the method of producing the microorganism of claim 8, while perhaps properly withdrawn by the Examiner, this claim is subject to rejoinder under

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MPEP § 821.04, upon allowance of product claim 8. Accordingly, claim 63 is withdrawn and rejoinder will be requested at an appropriate time.

#### **Amendments to the claims**

Claims 8 and 62, as well as withdrawn claim 63, have been amended to clarify that the recited activities are “endogenous” to the claimed microorganism. The endogenous property of the recited activities is described throughout the specification. For example, pages 3 and 4 describe microorganisms (including *Rhodococcus* species) that produce nitrilase, nitrile hydratase, or amidase enzymes; page 6 describes a *Rhodococcus* species with a nitrile degrading enzymatic system; and page 8, second full paragraph, describes *Rhodococcus* sp. ATCC39484 as a nitrile converting bacterium. In addition, the Examiner’s restriction requirement dated September 27, 2002, groups the inventions according to, *inter alia*, transformants (Group IV) and variants (Group II). Applicants had elected Group II drawn to variants, corresponding to the currently recited “mutants.” Thus the Examiner necessarily recognized the recited endogenous property of elected Group II from the specification.

Further, since Applicants had elected variants, and not transformants, the present amendments are not narrowing. These amendments are made to clarify that which was, and is, the inherent subject of the elected invention.

No new matter has been added.

Applicants respectfully request entry of the Amendment. Entry of the amendment is believed to be proper since the amendments do not raise new issues, the amendments merely clarify the subject matter previously under examination, which the Examiner has already acknowledged in the restriction requirement.

### **Information Disclosure Statement**

Initially, Applicants note that the Examiner has not yet provided a signed and initialed copy of Applicants' Form-1449 that accompanied the Information Disclosure Statement of February 27, 2004 (and corrected August 31, 2004). Applicants respectfully request that the Examiner consider and return the same. A copy of the corrected Form-1449 is attached hereto for the Examiner's convenience.

### **Claim Rejections Under 35 USC § 112, 1st Paragraph**

At page 2 of the Office Action, claims 8, 10, 60, 61, and 72 remain rejected under 35 USC § 112, first paragraph, as not complying with the written description requirement.

The Examiner states that Applicants' arguments filed June 6, 2004 were considered but not found persuasive. The Examiner believes that the claims encompass microorganisms having a wide range of enzyme structures and activities such that a representative number of such enzymes are not described in the specification sufficient to describe the subject matter of the present claims. (emphasis added)

The Examiner states that Applicants can overcome the rejection by amending the claims to recite the specific encoding nucleotide and/or amino acid sequences of the nitrilase, nitrile hydratase and amidase enzymes (SEQ ID NOS: 2, 4, 5, and 7).

### **Response to Written Description Rejection**

Independent claim 8 recites an isolated microorganism having an endogenous activity of converting a cyano group into a carboxyl group and being defective or reduced in an endogenous

activity of converting a cyano group into an amide group, wherein said microorganism is a mutant strain of a microorganism belonging to the genus *Rhodococcus*.

Under the written description requirement of 35 USC § 112, first paragraph, the description of the invention must clearly convey that the Applicant invented the subject matter which is ***claimed***, and must put the public in possession of what the Applicant ***claims*** as the invention. MPEP § 2163(I), citing, *In re Barker*, 559 F.2d 588, 592 (CCPA 1977); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997) (emphasis added).

As also provided by the MPEP, an Applicant may show possession of the claimed invention by describing the claimed invention with all its limitations using such descriptive means as ***words***, structures, figures, diagrams, and formulas. Further, possession of the claimed invention can be established, for example, by an actual reduction to practice or a description of whatever identifying characteristics sufficiently distinguish the claimed subject matter. See MPEP § 2163(I), citing, *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991); see also *Lockwood American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998); *Eli Lilly*, at 1568.

In the present case, Applicants are claiming an isolated, mutant ***microorganism*** of the genus *Rhodococcus* having an endogenous activity of converting a cyano group into a carboxyl group and being defective or reduced in an endogenous activity of converting a cyano group into an amide group.

Applicants have described the claimed microbe in such a way as to demonstrate to one skilled in the art that Applicants had possession of the claimed invention by describing the characteristics that distinguish it. For example, Applicants describe, in detail, an actual reduction

to practice (*Rhodococcus* sp. SD826 (see Tables 1-3 as well as Examples 1-3), and have deposited the exemplary embodiment (FERM BP-3705). Further, Applicants have described the scope of the claimed subject matter using terms and conventions of the art. For example, the specification describes: various *Rhodococcus* species and strains, and others are well-known in the art; the endogenous activities that are specifically present (converting a cyano group into a carboxyl group) and those that are specifically reduced or defective (converting a cyano group into an amide group). The Examiner is directed to pages 26 and 27 of the specification, providing a written description of numerous, exemplary substrates having a cyano group.

Further, microbes are often described in the art based upon their enzymatic properties, and thus, such descriptions are clearly sufficient to describe the distinguishing characteristics of novel microbes. See, e.g., Table 1 of Kato et al. (already of record).

Applicants appreciate the Examiner's position stemming from the decision in *Eli Lilly*, that the possession of isolated biological molecules, such as DNA or protein, often requires disclosure of nucleotide and/or amino acid sequences. ***However, Applicants are not claiming, nor even reciting, any isolated biological molecule.*** Instead, Applicants are claiming an isolated microorganism, and as such, may describe that microorganism by any means sufficient to identify the distinguishing characteristics (see above).

There is no requirement that claimed microorganisms be described by their genetic information. Such a requirement is a misinterpretation of the Federal Circuit's established law regarding the written description requirement, and would be an undue limitation on any such invention.

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Applicants respectfully submit that the claimed invention has been adequately described through an actual reduction to practice, deposit, and terms readily understood by those skilled in the art, and that describe the distinguishing characteristics of the claimed subject matter. Accordingly, reconsideration of this rejection is respectfully requested.

### Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

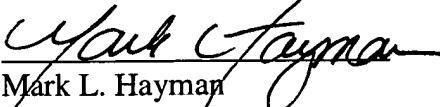
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**23373**

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